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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/594,972	06/15/2000	Ada Goerlach-Graw	BMID 9941 US	8671

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EXAMINER	
NGUYEN, BAO THUY L	

ART UNIT	PAPER NUMBER
1641	

DATE MAILED: 10/15/2003

16

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/594,972	Applicant(s) GOERLACH-GRAW ET AL.	
	Examiner Bao-Thuy L. Nguyen	Art Unit 1641	

-- Th MAILING DATE of this communication app ars on the cover sheet with the correspond nc address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 August 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *15-26* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *15-26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *17* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on August 28, 2003 has been entered.

2. Claims 15-26 are pending.

Claim Rejections - 35 USC § 112

3. Claims 15-26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 15 is vague because it is unclear what reagents, if any, are in the detection zone that would enable it to detect the analyte.

Claims 16-26, "An" should be replaced with -The- for clarity.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. Claims 15-17 and 20-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fitzpatrick et al (US 5,451,504) in view of Decker et al (US 4,230,683).

Fitzpatrick discloses a device and method for detecting the presence and amount of an analyte in a sample. The device of Fitzpatrick comprises a chromatographic strip having a sample contact zone, a trapping zone, and a detection zone. The sample contact zone contains mobilizable, labeled-receptor to the analyte. The trapping zone contains immobilized ligand (analyte or analyte analog) that will bind free receptor moving through the trap zone. And, the detection zone contains immobilized receptor that will bind the labeled-receptor/analyte complex enabling their detection therein. See columns 4-9 and figure 1. Fitzpatrick teaches labels such as colloidal gold or colored latex particles for use in the device. See column 8, lines 30-48.

Fitzpatrick differs from the claimed invention in failing to teach a universal conjugate.

Decker, however, teaches an improved method for detecting antigen by reacting a hapten-labeled antibody with the antigen, and then reacting the hapten moiety with a second, labeled anti-hapten antibody, and determining the amount of label bound to a solid support as a measure of the amount of the antigen in a sample. Decker teaches haptens such as digoxin as

appropriate for use in the hapten-labeled antibody. See column 1, lines 19-32, and lines 55-68. Decker teaches that the hapten-labeled antibody provides the advantages of amplifying the antigenicity of the bound antibody, thus, enabling an increased in binding of the antibody to the antigen. See column 2, line 34 through column 3, line 1.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Fitzpatrick by using the hapten-labeled method of Decker. Such a modification provides the advantage of amplifying the antigenicity of the bound antibody thereby increasing the sensitivity of the assay as taught by Decker. Further, a skilled artisan would have had a reasonable expectation of success in using the hapten-labeled antibody of Decker in the device of Fitzpatrick because such modification is a mere alternative and functionally equivalent labeling technique that is well known in the art. See Decker, column 1, lines 5-32. Additionally, since only the expected labeling effect would have been obtained, the use of alternative and functionally equivalent labeling techniques, such as taught by Decker, would have been desirable to those of ordinary skill in the art based on the economics and availability of components.

7. Claims 18, 19 and 24-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fitzpatrick in view of Decker as applied to claims 15-17 and 20-23 above, and further in view of Bernstein et al (US 5,824,268).

See the discussion of Fitzpatrick and Decker above. These references differ from the claimed invention in failing to teach an elution agent application zone located upstream of the sample application zone.

Bernstein, however, discloses a test device comprising a series of bibulous strips having a buffer zone, a sample zone, a reaction zone and a detection reagent zone, consecutively (column 6, lines 24-67). Bernstein teaches that the disclosed device provides the advantages of a simple test device where all the reagents, including liquid phase solvents, buffers, etc, necessary to perform the assay are incorporated and requiring only the additional of test sample. The placement of the various zones allows the appropriate addition of reagents and improves the assay results because the presence of the analyte can be determined in a sequential form of immunoassay. And, because all reagents are flowing simultaneously, the assay time will be shorter for any given result.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to further modify the device of Fitzpatrick as modified by Decker to include a buffer addition zone upstream of the sample addition zone such as taught by Bernstein. The inclusion of such a buffer addition zone provides the advantages of a simple test device where all the reagents, including liquid phase solvents, buffers, etc, necessary to perform the assay are incorporated and requiring only the additional of test sample. Further, Bernstein teaches that the placement of the various zones allows the appropriate addition of reagents and improves the assay results because the presence of the analyte can be determined in a sequential form of immunoassay. And, because all reagents are flowing simultaneously, the assay time will be shorter for any given result.

A skilled artisan would have had a reasonable expectation of success in modifying the device of Fitzpatrick to include a buffer addition zone as taught by Bernstein because Fitzpatrick teaches that more than three zones may be included in it's device (Fitzpatrick,

column 3, lines 27-37), and Bernstein teaches that it is advantageous to include all reagents necessary for an assay in one test device (Bernstein, column 3, lines 28-38).

Response to Arguments

8. Applicant's arguments filed August 28, 2003 have been fully considered but they are not persuasive.

Applicant argues that the instant invention differs from the device taught by Fitzpatrick because Fitzpatrick fails to disclose or suggest an element with two conjugate labels, and because Fitzpatrick teaches non-visible detectable labels such as enzymes and fluorophores, etc.

These arguments have been fully considered but are not deemed to be persuasive. First, in addition to indirectly visible labels, Fitzpatrick also teaches the use of latex and colloidal gold labels (column 4, lines 33-34). And second, while it is true that Fitzpatrick fails to teach an element with two conjugate labels, Fitzpatrick does teach that the choice of detection means can be made on the basis of convenience of the practitioner. Various detection means known in the art fall within the scope of the invention taught by Fitzpatrick (column 8, lines 54-57). Decker is cited for the disclosure of a universal detection system.

Applicant argues that Decker fails to cure the deficiencies of Fitzpatrick because Decker fails to teach direct visually detectable label, and that Decker does not teach a universal conjugate that comprises a second bioaffine binding partner and a direct visually detectable label. Applicant argues that there is no motivation to combine the teaches of Fitzpatrick and Decker because such a combination would leads to a system in which a binding partner for the analyte is labeled with a low molecular organic molecule that can be bound by another binding

partner for this low molecular organic molecule that in turn carries a label that is not directly visually detectable.

These arguments have been fully considered but are not persuasive. Fitzpatrick and Decker, together, disclose the claimed device in its entirety. Fitzpatrick teaches the claimed device with the exception of a universal labeling system comprising a first binding partner labeled with digoxin and a second binding partner specific for the digoxin conjugated to a detectable label. Fitzpatrick teaches labeling means including enzymes, fluorophores, chromophores, radioisotopes, dyes, colloidal gold, latex particles and chemiluminescent agents (column 8, lines 30-57). Decker teaches a universal labeling system comprising a digoxin labeled antibodies as binding partners and anti-digoxin antibodies conjugated to a label as the second partner. Therefore, a skilled artisan would have been motivated to modify the device of Fitzpatrick by using the universal conjugates taught by Decker for the advantages of amplifying the antigenicity of the bound antibody thereby increasing the sensitivity of the assay. Furthermore, because Fitzpatrick is generic with respect to the labeling system/means, a skilled artisan would have had a reasonable expectation of success in using the hapten-labeled antibody of Decker in the device of Fitzpatrick and to use a visually direct label because such modification is a mere alternative and functionally equivalent labeling technique that is well known in the art. See Decker, column 1, lines 5-32. Additionally, since only the expected labeling effect would have been obtained, the use of alternative and functionally equivalent-labeling techniques, such as taught by Decker, would have been desirable to those of ordinary skill in the art based on the economics and availability of components.

Applicant argues that Bernstein fails to cure the deficiencies of Fitzpatrick and Decker because neither Fitzpatrick nor Decker, alone or in combination disclose or suggest the element of claim 15. This argument is not persuasive for reasons stated above.

Conclusion

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao-Thuy L. Nguyen whose telephone number is (703) 308-4243. The examiner can normally be reached on Tuesday and Thursday from 9:00 a.m. - 5:00 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (703) 305-3399. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 and (703) 305-3592.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Bao-Thuy Nguyen
Primary Examiner
~~23 July 2003~~
13 October 2003